

REMARKS

Applicants thank the Examiner for the consideration given the present application. Claims 1 and 3-18 are pending. Claims 5-9 and 17 are presently amended. Claim 2 was cancelled previously. No new Claims have been added.

Specifically, Claims 5-9 and 17 have been amended to include the language "when compared to conventionally processed cocoa beans." Support for these amendments is found in Examples 1-3 and throughout the Specification. Additionally, Claims 5 and 17 have been further amended to include the modifying term "treated" before the product designation, such as, for example, roasted cocoa beans. Support for these amendments is found in table in Example 1 and throughout the Specification.

The Rejection under 35 U.S.C. §112

Claims 2-13 and 17-18 have been rejected under 35 U.S.C. § 112, second paragraph for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Specifically, the Examiner indicates that the term "reduced," is not clearly defined in the present claims.

The Examiner rejects Claims 5-13 and 17 for the use of the term "reduced" therein. Specifically, the Examiner states that "reduced" is a relative term which renders the claim indefinite because it is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention." The Examiner continues to say "[a] product, as it stands in its current state, cannot simply be "reduced," without reference to a standard or to the previous condition."

While Applicants respectfully disagree with the Examiner's characterization of the use of the term "reduced" herein, in a sincere effort to advance prosecution of the present application, Applicants have herein amended Claims 5-13 and 17 to further define the meaning of the term "reduced." For instance, Applicants have added the language shown in italics such that the Claim 5 now reads as follows: [a] product comprising *treated* roasted cocoa beans, wherein the level of acrylamide in said product is reduced by at least about 10% *when compared to conventionally processed cocoa beans*. See Claim 5, amended herein. Applicants respectfully assert that the present amendments to Claims

5-13 and 17 particularly point out and distinctly claim the subject matter of the invention and, therefore, overcome the rejection of these claims under §112, second paragraph.

The Provisional Obviousness-type Double Patenting Rejection

Claims 1 and 2-18 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting. Specifically, Claims 17 and 18 have been provisionally rejected as being unpatentable over Claims 13-14 of co-pending Application No. 10/603,978, and Claims 1 and 3-18 have been provisionally rejected as being unpatentable over the claims of co-pending Application No. 10/606,137. While Applicants respectfully disagree with the Examiner's characterization of the respective inventions of the foregoing applications, in a sincere effort to advance the prosecution of this case, included with this response is a Terminal Disclaimer, disclaiming the terminal part of the statutory term of any patent granted on the above-identified application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. §154 to §156 and §173 as presently shortened by any terminal disclaimer of co-pending Application Nos. 10/603,978 and/or 10/606,137. Accordingly, it is respectfully requested that the obviousness-type double patenting rejections be withdrawn.

Synopsis of the Invention

Recently, researchers discovered that acrylamide, a potentially cancer-causing chemical, is formed in many types of foods and beverages that undergo heat processing. Subsequently, it has been discovered that roasted cocoa bean products, such as chocolate, contain acrylamide. Acrylamide has a carcinogenic potency in rats that is similar to that of other carcinogens in food, but for humans, the relative potency in food and beverages is not known. See Specification, page 1.

While not being limited by theory, it is believed that the alpha-amine group of free asparagine reacts with a carbonyl source, forming a Schiff base. Under heat, the Schiff base adduct decarboxylates, forming a product that can either: (1) hydrolyze to form beta-alanine amide (which can, under heat, further degrade to form acrylamide) or (2) decompose to form acrylamide and the corresponding imine. (Applicants have

discovered that the circled precursor atoms comprise the carbons and nitrogens in acrylamide.) See Specification, page 3.

Applicants have found that adding an enzyme that hydrolyzes the amide group on the side chain of asparagine prior to final roasting of the cocoa beans reduces the level of acrylamide present in the roasted cocoa beans. While not being limited by theory, it is believed that the addition of such an enzyme degrades the side chain of asparagine, thus preventing the asparagine from forming acrylamide. In doing so, the amide bond is hydrolyzed and asparagine is converted to aspartic acid. See Specification, page 3.

The Rejection under 35 U.S.C. § 103

The Examiner has rejected Claims 1 and 3-18 under 35 U.S.C. § 103 as being unpatentable over Elder et al., Pub. No. 2004/0058054 (herein "Elder"). Specifically, the Examiner reasserts the arguments of the previous Office Action, which generally state that Elder teaches the reduction of acrylamide in cocoa.

The Examiner bears the burden of factually supporting any prima facie conclusion of obviousness. In determining the differences between the cited art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. See Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fe. Cir. 1983). Distilling the invention down to the "gist" or "thrust" of an invention disregards the requirement of analyzing the subject matter "as a whole." See W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983). Inventors of unobvious compositions, such as those of the present invention, enjoy a *presumption* of non-obviousness, which must then be overcome by the Examiner establishing a case of prima facie obviousness by the appropriate standard. If the Examiner does not prove a prima facie case of unpatentability, then without more, the Applicant is entitled to grant of the patent. See In re Oetiker, 977 F.2d 1443.

To establish a prima facie case of obviousness under 35 U.S.C. §103, the Examiner must meet three basic criteria. First, there must be some suggestion or motivation, either in the reference itself, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the cited reference must teach or suggest *all* the claim

limitations. See, for example, In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991). Appellants again respectfully assert that the Office Action fails to meet any of these criteria, and thus, fails to make a prima facie case of obviousness under 35 U.S.C. § 103.

First, there is no suggestion or motivation to modify the reference. Elder very generally discusses the reduction of acrylamide by using the term “inactivating the asparaginase.” See Elder [0011]. However, this broad claim, without more, does not provide the motivation necessary to make obvious the specific methods and compositions disclosed presently for actually reducing acrylamide in cocoa and cocoa beans. While Elder’s disclosure includes cocoa beans among a long list of examples of foods which contain acrylamide, at no time does Elder specifically teach how to reduce acrylamide in cocoa or cocoa beans. See Elder [0008]. Elder does not even claim reduction of acrylamide in cocoa beans, choosing instead to focus on rice, wheat, corn, barley and other like carbohydrates.

In sharp contrast to the ambiguous teachings of Elder, the present invention is clearly defined and supported in the specification, which not only provides a specific analytical method useful for reducing acrylamide in food products, but also provides numerous examples illustrating the use of that method to reduce acrylamide in cocoa products and cocoa beans. See, specification at pages 22-23. Thus, while Elder can show, by way of a single example, only that the level of acrylamide may be reduced in a laboratory setting, apart from any food product, and in particular, any cocoa product, the present Applicants have provided specific instances of acrylamide reduction in cocoa and cocoa beans.

Due to the lack of support for the theories presented therein, Applicants continue to respectfully assert that there is no suggestion or motivation to modify Elder such that the present invention is obvious in view thereof. For this reason alone, Applicants respectfully assert that a prima facie case of obviousness has not been established.

Second, there is no reasonable expectation of success as Elder fails to teach a method for acrylamide reduction in cocoa beans. As aforementioned, Elder generally discusses “inactivating asparagine” in foods, yet fails to provide any practical teachings relating thereto, even though the claims are directed to food products. The Examiner relies on paragraph [0011] of Elder to allegedly teach the reduction of acrylamide by contacting asparagine with asparaginase to decompose the asparagine into aspartic acid

ammonia. However, Applicants respectfully assert that the complex nature of food products, and in particular, cocoa and cocoa beans, does not permit Elder to speculate that such a reaction would necessarily occur in an actual food product simply because it occurred in a test tube. For this reason alone, Applicants respectfully assert that there is no likelihood of success and, therefore, a *prima facie* case of obviousness has not been established.

Moreover, there is no likelihood that the disclosure of Elder could provide a reduction in the level of asparagine in a food product (and particularly cocoa beans) by, for example, at least about 10%, at least about 30%, etc., up to at least about 90%, as presently taught and claimed by Applicants. See, for example, Example 2. Similarly, there is no teaching or suggestion in Elder of roasted cocoa beans that have acrylamide levels below about 350 ppb, down to a level below about 100 ppb, as presently taught and claimed by Applicants. See Specification, page 8. Rather, the Elder examples test only a chemical reaction (or the inhibition thereof) of a few chemicals independent of any food product. Specifically, Example 5 in Elder deals only with the combination of asparagine, glucose and asparaginase in a laboratory setting. (Notably this is the only example having anything to do with *preventing* acrylamide formation.) There is no showing that such an example is in any way representative of what would occur if the method disclosed therein was carried out using an actual food product. Without such a correlation, it cannot be said that Elder teaches the likelihood of success of Applicants independent claims. As a result, it cannot be said that Elder provides *any* likelihood that the findings presented therein could be produced in food products, and in particular, in cocoa and cocoa beans. Therefore, Applicants respectfully assert that because Elder merely sets forth very general teachings around acrylamide reduction, it provides no reasonable expectation of success of providing cocoa beans or cocoa products having reduced acrylamide levels. For this additional reason, Applicants respectfully assert that a *prima facie* case of obviousness has not been established.

Finally, there is no teaching of all the claim limitations. Applicants respectfully assert that the reference does not specifically teach, or provide an example of, reducing the level of asparagine/acrylamide in cocoa or cocoa beans, as presently claimed. Again, Applicants respectfully assert that simply disclosing the use of asparaginase does not amount to teaching the present invention, which describes a

specific method to reduce acrylamide in cocoa and cocoa products. The fact that Elder mentions cocoa beans among a list of food products that contain acrylamide hardly amounts to teaching a method for reducing the level of asparagine or acrylamide therein. Therefore, for this additional reason alone, Applicants respectfully assert that Elder fails to teach all the limitations of the present claims and fails to establish a prima facie case of obviousness.

Moreover, as discussed above, the Examiner has pointed to no teaching in Elder that suggests the specific claim limitations concerning the level of asparagine or acrylamide reduction, or the resulting level of acrylamide, in cocoa beans or products that are included in many of Applicants' claims. Clearly, Elder cannot be said to render obvious such claims, particularly in view of the very limited disclosure around how one reduces such levels of acrylamide. For this additional reason, Applicants respectfully assert that there is no teaching of all of the present claim limitations.


Findings of fact relied upon in making the obviousness rejection must be supported by substantial evidence within the record. See In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000). Applicants respectfully assert that, for all of the above reasons, the Examiner has failed to support the obviousness rejection with substantial evidence, and thus, has failed to establish a prima facie case of obviousness under 35 U.S.C. § 103. Therefore, Applicants respectfully request the rejection under 35 U.S.C. §103 be withdrawn.

CONCLUSION

In view of the foregoing, it is respectfully submitted that the Examiner's rejections under 35 U.S.C. §§ 112 and 103, as well as the provisional double patenting rejection, have all been overcome. Withdrawal of these rejections is respectfully requested.

Respectfully submitted,

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